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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,827	04/21/2004	Max R. Motyka	22306	5299

20551 7590 07/24/2006

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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,827	MOTYKA ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of Applicants remarks filed on 5/12/06.

Applicant's arguments filed 5/12/06 have been fully considered but they are not persuasive for the reasons of record and those stated below.

Claims 1-54 are pending.

Withdrawn rejections/objections:

1. Applicant has provided the Abstract on a separate sheet in compliance with 37 CFR 1.52(b)(4) and the objection is withdrawn.

2. Applicant has amended claims 5-10 to overcome the 35 USC 112, second paragraph rejection over lack of antecedent basis. The Examiner withdraws the rejection.

3. Applicant has filed a terminal disclaimer to overcome the provisional double patenting rejection of claims 1-13, 19-33, 38-42, 44-46, 48-51 and 53-54 which were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13, 17-30, 33-37, 40-46 and 49-51 of copending Application No. 10/829,468. The Examiner withdraws the rejection.

Maintained rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7 and 10 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamoto et al. (J. Am. Chem. Soc. 1961, 83(22), 4528-4532).

Instant claim 1 is drawn to a hypoallergenic metal amino acid chelate composition comprising a metal amino acid chelate including a naturally occurring amino acid chelated to a metal said amino acid to metal molar ration being from about 1:1 to 4:1.

Nakamoto et al. disclose thirty metal chelate compounds including eight different metal-glycine chelates including nickel, zinc, copper, cobalt, palladium, platinum and chromium (Abstract; page 4531, Table 1). Nakamoto et al. disclose a chromium-glycine chelate of the formula: $Cr(NH_2\text{-}CH_2\text{-}COO)_3\ H_20$; thus 3 glycine to 1 chromium ratio (Page 4531, Table 1).

Please note: With respect to the USC 102 rejection above and the rejections to follow, please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' hypoallergenic metal amino acid chelate composition differs and, if so, to what extent, from that of the

discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Claim Rejections - 35 USC § 102

Claims 1-4 and 12 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Lumb et al. (J. Phys. Chem. 1953, 57(7), 690-693).

Instant claim 12 is drawn to a calcium and glycine chelate where the ratio of calcium to glycine is 1:1.

Lumb et al. disclose the 1:1 chelate stability constants of calcium (instant claim 3) and glycine (instant claim 2) thus anticipating the instant composition (instant claims 1, 4 and 12) (page 692, right column "Chelate Stability Constants; and Table III).

Claim Rejections - 35 USC § 102

Claims 1-8, 19-21, 29-31, 38-40, 44-46, 48, 49 and 52-54 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Hsu (US 5,504,055).

Hsu discloses metal amino acid chelates that can deliver high levels of desirable metal ions to plants and human beings (Abstract; Column 1, lines 44-50). Hsu distinctly claims iron, copper, zinc, magnesium, manganese and calcium as metal ions and glycine as the amino acid thus anticipating instant claims 1-8 (Column 11, lines 45-52; Column 12; lines 12-14 and 18-24 and claims 7 and 8). The mole ratio of metal ion to

acid is about 1:2 (Column 2, lines 35-36). Hsu disclose a composition, and means to make the compositions, comprising ferrous iron carbonate/citric acid/glycine to produce an amino acid chelate thus anticipating the addition of citric acid (instant claims 19-21, 29-31, 53 and 54) (Column 3, lines 63-67 and column 4, lines 1-14). Hsu provides methods to synthesize the metal amino acid chelate (instant claims 38-40) (Column 3, lines 63-67 and Column 4, lines 1-14, for example). The Examiner interprets the selection of specific reagents by Hsu to produce the metal amino acid chelate as reading upon instant claims 39 and 40. Hsu administered the iron/citrate/glycine chelate to tomato plants (instant claim 46) (Column 7, lines 56-67 and column 8, lines 1-13). The Examiner interprets the selection of specific reagents by Hsu to produce the metal amino acid chelate for administration to tomato plants as reading upon instant claims 48 and 49. It is the Examiner's position that the method of Hsu et al. is the same as that claimed in instant claim 52, i.e., it results in the same composition.

Claim Rejections - 35 USC § 102

Claims 1-9, 11, 19, 22-24, 28-31, 38-40, 44-46, 48 and 49 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Ashmead et al. (US 6,426,424).

Ashmead et al. disclose compositions and methods of preparing amino acid chelates (Abstract). The amino acid ligand to metal molar ratio is from about 1:1 to 4:1 (Instant claim 1) (Column 5, lines 31-35 and column 10, lines 24-25). Ashmead et al. disclose iron, copper zinc manganese, cobalt, magnesium, chromium, and molybdenum

as metal ions and provide examples of a ferrous glycine chelate, zinc glycine chelate, manganese glycine chelate, magnesium glycine chelate, copper glycine chelate as well as mixed metal/amino acid chelates in the ratios of amino acid ligand to metal ion of 2:1 to 3:1 (instant claims 2-9 and 11)(Column 8, lines 8-25 and 48-67; column 9, lines 5-67 and column 10, lines 1-16). Ashmead et al. produced a metal amino acid chelate and added to the composition maltodextrin, corn-starch and cellulose (instant claims 19, 22-24, 28-31 and 38-40, 44 and 45) (Column 9, lines 29-32). Ashmead et al. disclose that the amino acid chelates can be administered to plants by dissolution on leaves or as a soil treatment thus anticipating instant claim 46 (Column 7, lines 53-63). Obtaining metal ions and amino acids to make the composition reads upon instant claims 48 and 49.

Claim Rejections - 35 USC § 102

Claims 1-4, 15-24, 26-31, 34-40, 43-49 and 52-54 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Ashmead et al. (US 4,725,427).

Ashmead et al. disclose a vitamin and mineral composition comprising amino acid metal chelate with an amino acid ligand to metal ratio of at least 2:1 and a method of preparing the vitamin and mineral composition (Column 5, line 61; column 11, lines 1-23 and lines 53-59; column 12, lines 1-36). The amino acid chelated minerals are selected from the group consisting of calcium, magnesium, iron, zinc, copper and manganese (Column 12, lines 18-22). Glycine is disclosed as an amino acid ligand (Column 5, lines 64-67). Thus, instant claims 1-4 are anticipated.

A powdered mixture of water soluble vitamins was prepared by blending calcium ascorbate folic acid thiamine mononitrate, sodium salt of riboflavin-5-phosphate, niacinamide pyridoxine HCl, biotin and calcium pantothenate (Column 9, lines 15-21). The powdered mixture was then blended with powdered lactose. Ascorbate is a salt of ascorbic acid. The Examiner interprets powdered lactose to be a maltodextrin and that maltodextrins can be both fillers and flow control agents thus reading on instant claims 19-24, 44 and 45. In a separate container, ethanol, propylene glycol, vegetable oil, vitamin A palmitate, vitamin D, vitamin E and cyanocobalamin were mixed until dissolution (instant claims 27) (Column 9, lines 24-34). The water-soluble vitamins were then added to the oil soluble vitamins and blended (Column 9, lines 35-43). To this mixture was added amino acid metal chelates and potassium amino acid complex thus reading on instant claims 26, 27, 29-31 and 38-40 (Column 9, lines 44-51). After blending, citric acid (instant claims 18 and 19), potassium bicarbonate and sodium bicarbonate, lime and lemon flavoring and aspartame sweetener (instant claim 28) were added and completely mixed and ultimately granulated (Column 9, lines 52-67). The granules dissolved in water to provide a pleasant tasting flavored drink thus reading on instant claims 15-18, 46, 48, 49, 53 and 54 (Column 2, lines 35-40 and column 10, lines 1-5). It is the Examiner's position that someone had to taste the composition and report on the flavor; any subject can be susceptible to allergens upon exposure to allergens; amino acids can be purchased in pharmaceutically pure form implicitly having no allergens thus reading on the method of instant claims 43 and 52. Subjects can inherently have allergies to at least one of soy, peanuts, tree nuts, crustaceans, finfish,

dairy, wheat, eggs, corn, gelatin, whey, chocolate, and strawberries. Ashmead et al. claim the method of preparing the composition (Column 11, lines 53-59 and column 12, lines 1-36 and claim 11).

Response to arguments:

Applicant contends that the composition of the instant invention is different than those found in Lumb, Nakamoto, Hsu, Ashmead '426 and Ashmead '427 because none of the references state that the metal amino acid chelates are hypoallergenic. Again the Examiner respectfully notes: "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' hypoallergenic metal amino acid chelate composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19 and 25 reamin/are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al. (US 5,504,055) in view of Cooper et al. (US 6,299,896).

The reference of Hsu et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Hsu et al. do not expressly disclose a composition wherein the formulation additive is a hypoallergenic flow control agent selected from the group consisting of fumed silica, stearic acid, talc, and combinations thereof.

Cooper et al. teaches a multi-vitamin nutritional supplement (Abstract). When preparing dosage forms incorporating the composition, the nutritional components are normally blended with conventional excipients such as the lubricant stearic acid.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the powder composition of Hsu et al. by adding a stearic acid lubricant as suggested by Cooper et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because stearic acid is a conventional lubricant added to dosage forms known by those of ordinary skill in the art. Cooper et al. disclose powders as a suitable dosage form (Column 9, line 62).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Claim Rejections - 35 USC § 103

Claims 1, 13, 14, 32, 33, 41, 42, 50 and 51 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashmead et al. (US 4,725,427) in view of Izumi et al. (Angew. Chem. Int. Ed. Engl. 1978, 17, 176-183).

The reference of Ashmead et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Ashmead et al. do not expressly disclose a composition and method wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared by: 1) a method other than protein hydrolysis; 2) protein hydrolysis and wherein the protein used in the hydrolysis is hypoallergenic.

Izumi et al. teach multiple methods of producing amino acids including enzymatic, fermentation, extraction (protein hydrolysis) and synthetic methods (Page 176, Table 1; page 177, 2.1 Extraction Method; 2.2 Fermentation Method; page 178, 2.3 Enzymatic method; and page 179, Synthetic Method).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to obtain amino acids via one of the methods suggested by Izumi et al. for the composition of Ashmead et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Izumi et al. state these methods are the recent advances in industrial production of amino acids (Page 176, middle of right column)

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Response to arguments:

Applicant argued that the hypoallergenic element required by all four independent claims is not taught by the cited references and the Examiner has not shown any references that teach a hypoallergenic chelate composition. Again the Examiner respectfully notes: "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

With respect to the method claims, the Examiner notes the affirmative hypoallergenic determination steps and respectfully submits that the methods are taught by the prior art for the reasons of record and those stated above.

In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' hypoallergenic metal amino acid chelate composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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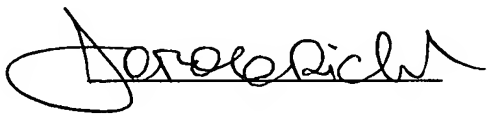

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